REMARKS

This is a Response to the Final Office Action mailed on October 16, 2009. The Office Action provided a three-month shortened statutory period in which to respond, ending on January 16, 2010. Accordingly, this Response is timely submitted. No fees are believed due with this Response. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 50-4498 in the name of Nestle Nutrition.

Claims 1, 6-8, 10-11 and 26-27 are pending in this application. Claims 2-5, 9 and 12-25 were previously canceled without prejudice or disclaimer. In the Office Action, Claims 1, 6-8, 10-11 and 26 are rejected under 35 U.S.C. §112; and Claim 27 is rejected under 35 U.S.C. §103. Applicant does not acquiesce in the correctness of the rejections or objections and reserves the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further, Applicant reserves the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application.

In the Office Action, Claims 1, 5-8, 10-11 and 26 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Specifically, the Patent Office alleges that "Applicants do not describe th[e] invention in such a manner that would enable one of ordinary skill in the art to use th[e] invention at the higher claimed range of about 15 to about 20 g [of an oligosaccharide blend] without undue burden." See Office Action, page 2.

Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement is whether the experimentation needed to practice the invention is undue or unreasonable. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also *United States v.*

Telectronics, Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.").

Applicant respectfully submits that because the breadth of the claimed invention is clear, the skilled artisan would be able to practice the claimed invention (i.e., make the claimed composition) without undue experimentation. Claim 1 recites a composition comprising an oligosaccharide blend that comprises fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS), wherein (a) the composition comprises from about 15 g to about 20 g of the oligosaccharide blend; (b) each of said oligofructose and oligogalactose are composed of chains with a degree of polymerization ranging from about 2 to about 7; (c) the weight ratio of FOS and GOS is from about 0.5 to about 20; and (d) the FOS and GOS are capable of synergistically promoting the growth of *Lactobacilli*, such that their combined prebiotic property is greater than the sum of their individual prebiotic properties.

The suitable range of FOS and GOS is clearly defined and can be used in any amount in the composition from about 15 g to about 20 g. The types of FOS and GOS are clearly defined in (b). The weight ratio of FOS and GOS are clearly defined in (c). Element (d) recites the characteristics that the combination of FOS and GOS provide when added to the composition to meet the requirements of (a), (b) and (c). As a result, the skilled artisan would be able to practice the claimed invention without undue experimentation because the skilled artisan has clearly defined parameters to use when making the claimed composition comprising the recited oligosaccharide blend.

Moreover, Applicant respectfully submits that compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, does not turn on whether an example is disclosed. An example may be "working" or "prophetic." A working example is based on work actually performed. A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved. An applicant need not have actually reduced the invention to practice prior to filing. See, MPEP 2164.02. Therefore, Applicant respectfully submits that, even if the Patent Office is correct that there are

no working examples that describe the use of from about 15 g to about 20 g of an oligosaccharide blend, such a requirement is not necessary. The present disclosure is still enabling because Applicant has provided a prophetic example of the claimed composition comprising from about 15 g to about 20 g of the oligosaccharide blend.

To support Applicant's proposed claims, the specification also specifically describes how the use of high levels of FOS may lead to excessive gas production in human volunteers. To avoid such potential disadvantages of high levels of FOS, Applicant has surprisingly found the prebiotic properties of FOS are significantly improved by the presence of GOS and that the effects of FOS and GOS are more than additive (i.e., a synergistic effect in promoting the growth of beneficial bacteria has been observed). As a result of the synergy, it is possible to obtain an equivalent or improved prebiotic effect of FOS at lower dosages. This has the advantage that a powerful prebiotic effect can be achieved in vivo while avoiding the need to ingest any single prebiotic at levels that could induce side effects. In addition, the maximum prebiotic benefit obtainable is superior to that gained from prebiotics individually. See specification, page 3, lines 11-26. As such, the present invention considers the disadvantages of providing too much of a certain type of fiber and discusses, in detail, how these disadvantages may be overcome by the present invention.

With respect to the state of the prior art, the Patent Office alleges that "[t]he art teaches that a single composition should not contain more than 10 g of fiber and Applicant['s] instant Examples do not contain more than 10g of fiber." The Patent Office also states that "[i]t is clear from the prior art above that amounts in a single composition above 10g give discomfort to a person." See Office Action, page 4. However, Applicant respectfully submits that the Patent Office mischaracterizes the nature of the claimed invention and the scope of the prior art.

The present invention specifically describes how the use of high levels of FOS may lead to excessive gas production in human volunteers. To avoid such potential disadvantages of high levels of FOS, Applicant has shown that the prebiotic properties of FOS as significantly improved by the presence of GOS and that the effects of FOS and GOS are more than additive (i.e., a synergistic effect in promoting the growth of beneficial bacteria has been observed). As a result of the synergy, it is possible to obtain an equivalent or improved prebiotic effect of FOS at

lower dosages. This has the advantage that a powerful prebiotic effect can be achieved in vivo while avoiding the need to ingest any single prebiotic at levels that could induce side effects. This utility is not considered by the prior art. In addition, the maximum prebiotic benefit obtainable is superior to that gained from prebiotics individually. See specification, page 3, lines 11-26. As such, the present invention considers the disadvantages of providing too much of a certain type of fiber and discusses, in detail, how these disadvantages may be overcome by the present invention, which overcome the problems discussed by the prior art.

Moreover, Applicant respectfully submits that simply because the prior art allegedly discloses that too much fiber may cause discomfort does not make the presently claimed subject matter un-enabled. Applicant notes that the prior art does not disclose or suggest that a specific oligosaccharide blend of fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS) may cause discomfort. In fact, the prior art only states that too much fiber may cause discomfort. As a result, the prior art has not even considered the beneficial effects of the oligosaccharide blend in accordance with the present blends. The prior art fails to even consider that there may be combinations of fibers that do not provide discomfort despite the assertion by the Patent Office.

Additionally, the enablement requirement requires only that practicing the claimed invention not be unduly burdensome for the skilled artisan. It does not require that administration of a composition results in no adverse side effects. In fact, many patented drugs, pharmaceuticals and nutritional supplements can cause adverse side effects. Therefore, while Applicant does not admit that administration of the presently claimed compositions may cause discomfort and, in fact, submits that the opposite is true and the presently claimed compositions result in synergistic effects in promoting the growth of beneficial bacteria, Applicant submits that it is irrelevant whether the prior art indicates that more than 10g of fiber may cause discomfort. Indeed, such a teaching would actually lead the skilled artisan down a path divergent from the presently claimed subject matter in view of such a disclosure. Accordingly, the prior art would actually teach away from the presently claimed subject matter.

Finally, with respect to the quantity of experimentation, the Patent Office continues to assert that "a burdensome amount of research would be required by one of ordinary skill in the art to bridge [the] gap" between a composition comprising 2g, 2.5g, and 9.86g and a composition

comprising about 25g, about 20g or about 15g of fiber. See, Office Action, page 6, line 19-page 7, line 1. However, Applicant respectfully disagrees. Instead, as previously discussed, Applicant notes that specific amounts of specific ingredients for use in the present compositions are clearly set forth in the specification. Among those specific amounts of ingredients, a composition comprising from about 15 g to about 20g of fiber is clearly set forth in the specification.

Accordingly, because the Patent Office admits that the relative skill of those in the art is very high (e.g., Ph.D and M.D. level technology), Applicant respectfully submits that the skilled artisan would be more than capable of measuring from about 15 g to about 20 g of fiber to include in a composition comprising both FOS and GOS in the presently claimed ratios and test whether this amount provided a synergistic effect over individual FOS, GOS or other oligosaccharide. Indeed, the relative skill of a Ph.D or an M.D. is not even required to be able to create a composition according to the present claims that include from about 15 g to about 20 g of the oligosaccharide blend. Rather, anyone capable of adding FOS and GOS to a composition in an amount required by (a), (b) and (c) can practice the claimed invention.

For at least these noted reasons, Applicant respectfully submits that the present claims are fully enabled by the specification and would not require a burdensome amount of experimentation for the skilled artisan to obtain compositions according to the present claims. Accordingly, Applicant respectfully requests that the rejection of Claims 1, 5-8, 10-11 and 26 under 35 U.S.C. §112, first paragraph, be reconsidered and withdrawn.

In the Office Action, Claim 27 is rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,399,124 to Lesens et al. ("*Lesens*") in view of U.S. Patent Publication No. 2003/0138476 to Van Leeuwen et al ("*Van Leeuwen*"). Applicant respectfully traverses the rejection for at least the reasons set forth below.

Independent Claim 27 recites, in part, a composition comprising glutamine and an oligosaccharide blend that consists essentially of fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS), wherein the weight ratio of FOS and GOS is from about 0.5 to about 20 and wherein the FOS and GOS are capable of synergistically promoting the growth of

Lactobacilli. In contrast, the cited references fail to disclose or suggest each and every element of independent Claim 27.

As discussed above, the present invention specifically describes how the use of high levels of FOS may lead to excessive gas production in human volunteers. To avoid such potential disadvantages of high levels of FOS, the present invention has shown that the prebiotic properties of FOS as significantly improved by the presence of GOS and that the effects of FOS and GOS are more than additive (i.e., a synergistic effect in promoting the growth of beneficial bacteria has been observed). As a result of the synergy, it is possible to obtain an equivalent or improved prebiotic effect of FOS at lower dosages. This has the advantage that a powerful prebiotic effect can be achieved in vivo while avoiding the need to ingest any single prebiotic at levels that could induce side effects. In addition, the maximum prebiotic benefit obtainable is superior to that gained from prebiotics individually. See, specification, page 3, lines 11-26. As such, the present invention considers the disadvantages of providing too much of a certain type of fiber and discusses, in detail, how these disadvantages may be overcome by the present invention. In contrast, Applicant respectfully submits that *Lesens* fails to disclose each and every limitation of the present claims.

Lesens and *Van Leeuwen* alone or in combination fail to disclose or suggest compositions comprising glutamine and an oligosaccharide blend as required by Claim 27. *Lesens* and *Van Leeuwen* alone or in combination also fail to disclose or suggest an oligosaccharide blend that consisting essentially of fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS) having a weight ratio from about 0.5 to about 20 as required by Claim 27.

Lesens is directed to frozen desserts that contain lactic acid bacteria and dietary fibers and its benefit to the human health after consumption of the frozen desserts. *Lesens* fails to disclose or suggest the use of glutamine at any place in the disclosure. Such a bioactive compound is known to have health benefits, especially with respect to the gastrointestinal tract. Further, *Lesens* also fails to disclose or suggest compositions having an oligosaccharide blend consisting essentially of FOS and GOS at the weight ratio in accordance with independent Claim 27. Instead, *Lesens* discloses compositions having either FOS or GOS, but not both and not at the claimed ratio. Indeed, the Patent Office fails to point to any specific disclosure in *Lesens* with

respect to these elements. As a result, *Lesens* fails to recognize the advantages, benefits and/or properties of the claimed oligosaccharide blend in accordance with the present claims.

The Patent Office asserts that it would have been obvious to one of ordinary skill in the art to make a composition of FOS and GOS in a specific ratio. As support for this statement, the Patent Office asserts that "Examples 4-5 of *Lessens* et al teach a cone made of Raftilose L30 (table 7) or wafer dough of galactooligosaccharide P7L, respectively; and a decoration or coating such as that of Table 3 (galactooligosaccharide P7L) or Table 4 (Raftilose L30). However, the Examples cited by the Patent Office as disclosing the use of either FOS or GOS do not even use the FOS and GOS in the same compositions, let alone the FOS and GOS used in the same compositions as an oligosaccharide blend. At best, *Lesens* discloses that an aerated ice creams may be dipped into compositions having GOS (Table 3) or FOS (Table 4), or that ice cream may be contained in a wafer dough containing FOS (Examples 4-5) or GOS (Example 5). At no place in the disclosure does *Lesens* disclose the use of FOS and GOS in an oligosaccharide blend. In fact, *Lesens* never discloses that the FOS and GOS are used in the same composition, let alone as an oligosaccharide blend of a specific amount, or as an oligosaccharide blend consisting essentially of those two oligosaccharides as required, in part, by the present claims.

Van Leeuwen is directed to the use of glutamic acid for the preparation of a nutritional preparation that is intended for use for the treatment or prevention of excess or undesired permeability of the intestinal wall. *Van Leeuwen* specifically fails to disclose or suggest compositions having an oligosaccharide blend consisting essentially of FOS and GOS at the weight ratio in accordance with independent Claim 27. Instead, *Van Leeuwen* discloses compositions having either FOS or GOS, but not at the claimed ratios. Indeed, the Patent Office fails to point to any specific disclosure in *Van Leeuwen* with respect to the recited elements.

For at least these noted reasons, *Lesens* and *Van Leeuwen* alone or in combination fail to disclose suggest each and every element of independent Claim 27. Moreover, *Lesens* and *Van Leeuwen* fail to recognize the advantages, benefits and/or properties of the claimed oligosaccharide blend in accordance with the present claims. Accordingly, Applicant respectfully requests that the obviousness rejection of Claim 27 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

For the foregoing reasons, Applicant respectfully requests reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Patent Office is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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